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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/074,116	02/12/2002	German A. Valcarce	101141-12	8300
27387	7590	12/15/2003	EXAMINER	
BRUCE LONDA NORRIS, MCLAUGHLIN & MARCUS, P.A. 220 EAST 42ND STREET, 30TH FLOOR NEW YORK, NY 10017			WEBER, JON P	
			ART UNIT	PAPER NUMBER
			1651	

DATE MAILED: 12/15/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/074,116

Applicant(s)

VALCARCE, GERMAN A.

Examiner

Jon P Weber, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16 and 23-28 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-16 and 23-28 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
- a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: .

Status of the Claims

Claims 1-16 and 23-28 have been presented for examination.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-3, drawn to a cell free ciliate extract comprising Δ -7 and Δ -22 cholesterol desaturases, classified in class 435, subclass 189, for example.
- II. Claim 4, drawn to a method of making Δ -7 dehydrocholesterol with a cell free extract comprising Δ -7 and Δ -22 cholesterol desaturases, classified in class 435, subclass 61, for example.
- III. Claims 5-7, drawn to a pure Δ -7 cholesterol desaturase (E.C. 1.3.1.21, RN 9080-21-1), classified in class 435, subclass 189, for example.
- IV. Claims 8-10, drawn to Δ -22 cholesterol desaturase (no EC assigned, RN 110183-45-4), classified in class 435, subclass 189, for example.
- V. Claims 11-13, drawn to a process for making a pure Δ -7 cholesterol desaturase, classified in class 435, subclass 189, for example.
- VI. Claims 14-16, drawn to a process for making a pure Δ -22 cholesterol desaturase, classified in class 435, subclass 189, for example.
- VII. Claims 23-25, drawn to drawn to a method of making Δ -7 dehydrocholesterol with a pure Δ -7 cholesterol desaturase, classified in class 435, subclass 61, for example.

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VIII. Claims 26-28, drawn to a method of making Δ -7, Δ -22-bis-dehydrocholesterol with pure Δ -7 and pure Δ -22 cholesterol desaturases, classified in class 435, subclass 61, for example.

The inventions are distinct, each from the other because of the following reasons:

Inventions III and V; and IV and VI are related as process of making and product made.

The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case many different methods of purifying enzymes are known in the art. It is an arbitrary matter of experimental design choice which methods are used. Typically electrophoretic methods might be used instead of chromatographic.

Inventions I, III and IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are each drawn to different enzyme compositions: a crude extract containing two activities, and to separately purified forms of each of the two activities. Each enzyme has a different activity, the combination of the two has a distinct activity from either one separately.

Inventions II, V, VI and VII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case these are two different methods of making Δ -7, Δ -22 or Δ -7, Δ -22 -dehydrocholesterols using

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different combinations of enzymes. Different products result from the different methods and enzyme combinations.

Inventions I and II; and III and VII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case these pairings show alternate methods of making the product from different enzyme compositions. The product could be made by ordinary chemical means.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their somewhat different classification, the search required for one Group is not required for other Groups, and the Groups have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper. It is recognized that some of the Groups have overlapping classification due to the broad encompassing classification system. However, each of these Groups and enzymes would require separate searching especially in the non-patent literature as evidenced by the separate RNs for the enzymes.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

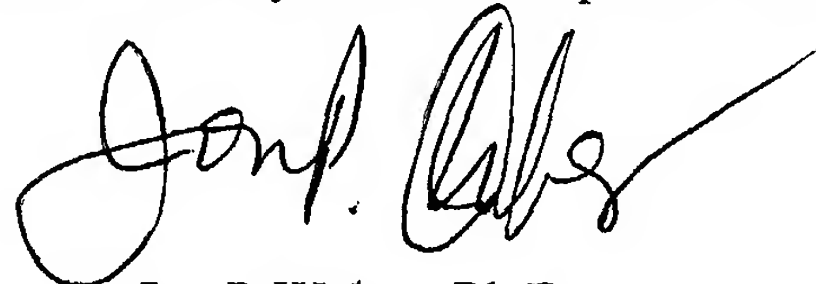
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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jon P Weber, Ph.D. whose telephone number is 703-308-4015. The examiner can normally be reached on daily, off 1st Fri, 9/5/4.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Wityshyn can be reached on 703-308-4743. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

My new Office room number will be Rem-03A45 and my new Office phone number will be 571-272-0925 after 15 January 2004.



Jon P Weber, Ph.D.
Primary Examiner
Art Unit 1651

JPW
10 December 2003